

Amendment
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Remarks

Upon entry of this amendment, claims 97- 98 and 103 - 108 are pending. Claim 104 has have been amended, and claims 105 - 108 have been added by this amendment.

Amendments to the Specification

In the specification, page 16, 2nd paragraph (appearing at publication ¶ [0048]) has been amended to correct a clerical error. This amendment was the subject of a prior request for amendment, dated 2/1/05. However, as noted in the Office communication of August 25, 2006, at page 3, that amendment incorrectly stated that the amendment was to page 14, 2nd paragraph, rather than to page 16, 2nd paragraph. This amendment corrects that prior misstatement.

Amendments to the Claims

Support for claim 104 as amended can be found throughout the specification, particularly in the specification at page 6, lines 1 et seq. (publication ¶ [0012], and page 15, line 15 - page 16, line 9 (publication ¶ [0046]). No new matter has been added.

New Claims

Support for the new claims can be found throughout the specification, particularly in the specification at page 16, lines 24 et seq. (publication ¶ [0048] and page 25, lines 9 - 13 [0061]. No new matter has been added.

Rejections under 35 U.S.C. § 112, ¶1

Claims 97-98 and 103-104 are rejected under 35 U.S.C. § 112, ¶1 as failing to satisfy the written description requirement. Applicant respectfully traverses and, for the following reasons, requests reconsideration and withdrawal of this rejection to the pending claims as amended.

To comply with the written description requirement, "the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996) at p. 1570. Finding the same wording (*ipsis verbis*) used in the claim is not necessary. *Id.* Thus, so long as a person "of ordinary skill in the art would have understood the inventor to have been in possession of the

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claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996) at p. 1175. "... [H]ow the specification accomplishes this is not material." *Id.* At p. 1172 (citing *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976).

Claim 104, as amended -the principal independent claim, relates to a composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid/salt thereof, cancellous bone, demineralized bone matrix (DBM), and non-decalcified bone matrix (NBM). Clearly, the instant disclosure demonstrates *applicant had possession of the invention* embodied in claim 104. As indicated in the Offices' prior communication (Communication of May 24, 2006, at ¶ 2), the disclosure directly supports a composition consisting essentially of the three ingredients of a hyaluronic acid/salt, cancellous bone and demineralized bone matrix. (see May 24, 2006 Communication, ¶. 2, citing, e.g., to publication ¶. [0012], last three sentences, and to original claim 56.)

Claim 104 adds to this three-component composition, non-decalcified bone matrix (defined at publication para. [0028]). Yet the use of the combination of NBM and DBM, in lieu of DBM alone as a composition constituent, for its osteoinductive advantages is expressly provided for at publication ¶ [0046]. As stated there: "A combination of non-decalcified bone matrix protein and DBM is also useful in the invention compositions as a source of osteoinductive molecules." (Noting that the acid treatment of DBM leaches out certain osteogenic molecules when DBM is used alone.) Hence, the disclosure clearly demonstrates to one skilled in the art applicant's possession of the invention as embodied in amended claim 104 (with the combination of NBM and DBM noted above in lieu of the DBM alone as the osteoinductive component of the composition appearing at ¶ [012] and original claim 56. Moreover, as also noted above, the other elements of each of the claims dependent on claim 104, are expressly disclosed in the specification (see, e.g., publication ¶ [0048] and [0061]. Accordingly, adequate written description having been demonstrated for amended claim 104 and the remaining claims, applicant urges that the rejection under 35 U.S.C. § 112, ¶1 be withdrawn and the claims allowed to issue without delay.

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Conclusion

Applicant respectfully requests withdrawal of the rejections and believes that the claims as presented represent allowable subject matter. If the Examiner desires, applicant welcomes a telephone interview to expedite prosecution and is available at the telephone number below. applicant believes there is no fee due at this time. However, the Commissioner is hereby authorized to deduct any deficiency or credit any overpayment to Deposit Account No. 19-3140.

Dated: October 20, 2006

Respectfully submitted,



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